



851 Broken Sound Parkway NW  
Boca Raton, FL 33487-3693  
(561) 241-9400  
Fax (561) 995-5188  
Email Address: RSRegDpt@aol.com

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BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Elizabeth A. Yetley, Ph.D., R.D., Director  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW, HFS-450  
Washington, DC. 20204

Dear Dr. Yetley:

Rexall Sundown, Inc. ("Sundown") wishes to notify the Food and Drug Administration that it has marketed or will within the near future commence marketing dietary supplements which bear statements of nutritional support, pursuant to Section 6 of the Dietary Supplement Health and Education Act ("DSHEA"), Section 403(r) of the Federal Food and Drug Cosmetic Act ("the Act"). Please see the attachment for a listing of the dietary supplements and corresponding statements of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403(r)(6)(C) of the Act. Two copies of this cover letter and its attachment are enclosed.

Very truly yours,

*Deborah Shur Trinker*

Deborah Shur Trinker  
Director of Regulatory Affairs  
and Corporate Counsel

DST/mw

Attachment

975-0162

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DIETARY SUPPLEMENT	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
<b>Combination Product</b> (Claims for Beta-Carotene, Vitamin C, Vitamin E, Riboflavin, Vitamin B-6, FloraGLO®, Lutein, Bilberry, BioPerine®, Eyebright, Alpha Lipoic Acid, Glutathione, Spinach)	Vision Essentials™	A Dietary Supplement for maintaining optimum eye health and function; as we mature in years, we may begin to notice subtle changes in our vision. Such vision changes are assumed to be a normal and expected part of growing older. However, with recent breakthroughs in research on health and longevity, we have learned that we can take positive action to promote and maintain healthy eye function. Routine evaluations by a physician, a healthy, active lifestyle and proper nutrition all play a vital role in eye health. Rexall Showcase International's new Vision Essentials™ formula contains some of the most useful nutrients to support and maintain the health of your eyes.
<b>Creatine Powder -</b> (Claims for Creatine Monohydrate)		Promotes muscular energy and helps delay fatigue during exercise; creatine is a compound that is synthesized in the body and stored in muscle tissue where it is converted to Creatine Phosphate (CP) and is used to provide energy to working muscles. Creatine helps delay muscular fatigue and enhances recovery after exercise, particularly in individuals with lower Creatine levels. Creatine may also play a stimulatory role in muscle tissue after a period of inactivity.
<b>Combination Product -</b> (Claims for Vitamin C, Vitamin D, Vitamin B-6, Folic Acid, Vitamin B-12, Calcium, Iron, Magnesium, Zinc, Selenium, Copper, Manganese, Molybdenum, Potassium, Silicon, Boron)	Women's Formula 1	Developed specifically for women's nutritional needs; created as an integral part of a nutritional program to meet the specific needs of women.
<b>Combination Product -</b> (Claims for Vitamin C, Vitamin D, Vitamin K, Vitamin B-6, Folic Acid, Vitamin B-12, Calcium, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Molybdenum, Potassium, Silicon, Betaine HCl, Boron)	Women's Formula 2	Developed specifically for women's nutritional needs after menopause; created as an integral part of a nutritional program to meet the specific needs of women after menopause.
<b>St. John's Wort - Thompson</b> (Claims for Standardized extract 0.3% Hypericin)		Helps assist in mood enhancement; St. John's Wort is perennial shrub native to Europe and found throughout the United States. The leaves and flowers contain the active compound hypericin. Hypericin helps assist in mood enhancement, promoting a calming and soothing sense of well-being.
<b>St. John's Wort - Sundown</b> (Claims for Standardized Extract 0.3% Hypericin)		Helps assist in mood enhancement; St. John's Wort is a perennial shrub native to Europe and found throughout the United States. The leaves and flowers contain a variety of active compounds such as hypericin, flavonoids and tannins. Hypericin helps enhance mood by promoting a calming and soothing sense of well-being.

DIETARY SUPPLEMENT	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
Combination Product - Rexall (Claims for Glucosamine, Vitamin C, Zinc, Manganese, and Copper)		Helps repair cartilage and promotes healthy joint function.

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